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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,212	10/30/2003	David R. Hennings	NSL-501	2780

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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,212

Applicant(s)

HENNINGS ET AL.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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At the outset it is noted that applicant waste that claims 1-24 are pending. The examiner respectfully notes that with the current amendment, claims 18 and 24 are cancelled and new claim 25 is pending.

Applicant's amendments have remedied the rejection under 35 U.S.C. 112, second paragraph.

With regard to Goldman et al ('084) applicant argues that Goldman et al ('084) do not teach use of a laser with an output in the 1.2 to 1.8 micron range and does not teach heating and shrinking collagen to destroy endothelial cells. The examiner respectfully notes that this is why Goldman et al ('084) was not applied under section 102 of the statute. With regard to the particular effect on endothelial cells, it is respectfully noted that endothelial cells are one of the layers comprising blood vessel walls, official notice thereof is hereby taken, thus, the treatment of Goldman et al ('084), which coagulates the vessel (see e.g. Goldman et al ('084), column 2, lines 40-52), must inherently act on the epithelium thereof. Further regarding Goldman et al ('084) applicant makes the assertion "localized necrosis and destruction of the undesirable varicose veins is possible with the present invention. In Goldman, using RF energy to cause ablation and necrosis is neither anticipated nor is it possible. In Goldman, the anticipated result is ligation." (see the instant response, page 12, the latter portion of the second full paragraph thereon). The examiner respectfully submits that applicant has misinterpreted the teachings of Goldman et al ('084). Applicant's attention is respectfully invited to the above cited passage of Goldman et al ('084), which states that the "ligation" mentioned therein involves coagulation. As well known in the art coagulation is actually ablation of tissue, this is shown for example by the disclosure of Motamedi et al (included for applicant's convenience) at column 1, lines 24-39.

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Thus clearly, to one having ordinary skill in the art, Goldman et al ('084) teach the ablation or destruction of the venous tissue, by requiring the coagulation thereof in the process of ligation.

With regard to the section of the response headed "Remark 6:" the examiner notes that paragraphs (a)-(c) of the remarks therein do not distinguish applicant's comprising-type claim from Goldman et al ('084). While paragraph (d), disregards the teaching of providing total collapse, closure and obstruction of this vessel, therein.

Regarding Dew et al, the examiner must firstly point out that Dew et al has not been applied as an anticipatory reference. The examiner further respectfully but vigorously transgresses applicant's characterization that "Dew et al does not suggest that such [1.32 micron] laser energy may be directed through a fiber optic delivery device" (see the instant response, page 13, the last sentence) as a careful reading of column 6, lines 11-43 of Dew et al will reveal that this is a precisely what is being taught, among other things.

Regarding the combination of Dew et al and Goldman et al ('084) applicant asserts that because Dew et al does not teach necrosis and provides thermal regulation, it cannot be combined with Goldman et al ('084). However, Goldman et al ('084) provide for the ablation of the blood vessel and also teach thermal control (see above), and Dew et al state that the thermal effect can be controlled by selection of electro-optical parameters (see Dew et al column 6, lines 55-68). Thus Dew et al need not teach the destruction of vessels per se.

Applicant argues that Roth et al. Conn, and Makower are all directed to prostate treatment and are thus inapplicable to the present invention. The examiner must respectfully disagree. Roth et al is directed to heating tissue, including exsanguinated blood vessels to provide necrosis thereof and as such is properly combined with Goldman et al ('084) and regardless, Goldman et

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al ('084) teach pulling back the catheter and this pull back rate is well within the scope of one having ordinary skill in the art. With regard to the teachings of Conn et al and Makower, these relate to the metering of laser application to heat tissue, and as such are also properly combined. With regard to the apparatus claims, while Makower may not specifically teach the same intended use for the device, as does applicant, the presence of the claimed structure therein renders it wholly appropriate to apply to the claims.

The examiner respectfully submits that applicant's reliance on *ACS Hospital Systems* is misplaced, as the rejections all include references that suggest the combinations as set forth above.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 6, 7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al. Goldman et al ('084) teach a method as claimed, but do not specify a wavelength. Dew et al teach the desirability of using 1.3 micron radiation to treat tissue. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take it's place, thus producing a method such as claimed.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Roth et al. Roth et al teach employing pull back rate as claimed, noting that the desired rate is dependent on the laser energy. It would have been obvious to the artisan of ordinary skill to

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employ a pull back as claimed, since these are known in the art and provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art official notice of which is hereby taken, thus producing a method such as claimed.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed, it would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue, while thus producing a method such as claimed.

Claim 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Dew et al as applied to claims 1, 2, 6, 7 and 25 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using infrared sensing. It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed.

Claim 14-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the device of Makower et al, since Makower et al teach the use of an

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Nd:YAG laser, which necessarily produces this radiation, as taught by Dew et al and to employ the pull back mechanism of Roth et al, since this enables uniform treatment along the surface, as taught by Roth et al, thus producing a device such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et al and Roth as applied to claims 14-17 and 20-23 above, and further in view of Conn et al. Conn et al teach a diffusing tip on an introducer for a fiber. It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et al, thus producing a device such as claimed.

Applicant's arguments filed August 12, 2004 have been fully considered but they are not persuasive, for the reasons set forth above. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number (571) 272-4773.



DAVID M. SHAY
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GROUP 330